**SUNITINIB**

| Generic | Brand | HICL | GCN | Exception/Other |
|---|---|---|---|---|
| SUNITINIB MALATE | SUTENT | 33445 | | |

**This drug requires a written request for prior authorization.**

**GUIDELINES FOR USE**

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC)?

   If yes, **approve for 12 months by HICL with a quantity limit of #1 per day.**
   **APPROVAL TEXT:** Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, continue to #2.

2. Does the patient have a diagnosis of gastrointestinal stromal tumor (GIST) **AND** meet the following criterion?
   - The patient has had a previous trial of or contraindication to imatinib mesylate (Gleevec)

   If yes, **approve for 12 months by HICL with a quantity limit of #1 per day.**
   **APPROVAL TEXT:** Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, continue to #3.

3. Does the patient have a diagnosis of unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET) **AND** meet the following criterion?
   - The patient's tumor is progressive and well-differentiated

   If yes, **approve for 12 months by HICL with a quantity limit of #1 per day.**
   **APPROVAL TEXT:** Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, continue to #4.

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## SUNITINIB

### GUIDELINES FOR USE (CONTINUED)

4. Is the request for adjuvant treatment of renal cell carcinoma and meet **ALL** of the following criteria?
   - Patient is at least 18 years old
   - Patient is at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy

   If yes, **approve for 12 months by HICL with a quantity limit of #1 per day.**
   **APPROVAL TEXT:** Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.
   If no, do not approve.
   **DENIAL TEXT:** The guideline named **SUNITINIB (Sutent)** requires a diagnosis of advanced renal cell carcinoma (RCC), gastrointestinal stromal tumor (GIST), unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET), or for adjuvant treatment of renal cell carcinoma. In addition, the following must be met:
   **For diagnosis of gastrointestinal stromal tumor (GIST), approval requires:**
   - The patient has had a previous trial of or contraindication to imatinib mesylate (Gleevec)

   **For diagnosis of unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET), approval requires:**
   - The patient's tumor is progressive and well-differentiated

   **For adjuvant treatment of renal cell carcinoma, approval requires:**
   - Patient is at least 18 years old
   - Patient is at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy

### RATIONALE
Ensure appropriate utilization of sunitinib based on FDA approved indication.

### FDA APPROVED INDICATIONS
Sutent is a kinase inhibitor indicated for the treatment of:
- Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate
- Advanced renal cell carcinoma (RCC)
- Progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease
- Adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy

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## SUNITINIB

### FDA APPROVED INDICATIONS (CONTINUED)

### DOSAGE AND ADMINISTRATION

**GIST and Advanced RCC:**

- 50 mg orally once daily, with or without food, 4 weeks on treatment followed by 2 weeks off.

**Adjuvant RCC:**

- 50 mg orally once daily, with or without food, 4 weeks on treatment followed by 2 weeks off for nine 6-week cycles.

**pNET:**

- 37.5 mg orally once daily, with or without food, continuously without a scheduled off-treatment period.

Dose Modification:

- Dose interruptions and/or dose adjustments of 12.5 mg recommended based on individual safety and tolerability.

### REFERENCES

- Pfizer Labs. Sutent package insert. New York, NY. November 2017.

| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 01/01/18

Created: 05/11
Client Approval: 12/17

P&T Approval: 11/13